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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	Michael Griffin Hayek	Examiner:	Shengjun Wang
Serial No.:	09/291,227	Group Art Unit:	1617
Filed:	April 13, 1999	Docket:	1448.019US1
Title:	LUTEIN - CONTAINING SUPPLEMENT AND PROCESS FOR ENHANCING IMMUNE RESPONSE IN ANIMALS		

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8-27-02

**DECLARATION OF MICHAEL GRIFFIN HAYEK UNDER 37 C.F.R. § 1.132**

I, Michael Griffin Hayek, state and declare as follows:

1. I am Director, Strategic Research, with The Iams Company, Lewisburg, Ohio. My principal job responsibility is as a researcher investigating animal nutritional products and methods for improving animal health.

2. I have been continuously employed by The Iams Company since April 1, 1995. Prior to working at The Iams Company, I was a Postdoctoral Fellow at the U.S.D.A. Center of Aging at Tufts University from May 1991 until May 1995. I have conducted considerable research in areas such as nutrition and animal health.

3. I have a Ph.D. degree in Interdisciplinary Nutrition from the University of Kentucky, Lexington, Kentucky, 1991; and a Masters of Science degree in Animal Science from the University of Kentucky, Lexington, Kentucky, 1987. I have published about 31 papers in peer reviewed journals concerned with nutritional biochemistry. I have been named as an inventor or co-inventor on about 7 U.S. Patents in the field of Companion Animal Nutrition.

4. I am the named sole inventor on the above-referenced patent application which claims diet-based processes for:

enhancing the immune response of a companion animal, such as a dog or cat  
(Claims 1, 3, 4, 5, 6, 7, and 8);

increasing the lutein concentration in the circulating blood of a companion animal(Claim 9);

increasing the immunoglobulin concentration in a companion animal(Claim 10);  
and

increasing the lymphocyte cells in a companion animal(Claim 11).

5. These processes involve feeding the companion animal in need of such treatment a diet containing an effective amount of a lutein supplement. The diets can contain, for example, from about 1 to about 50 mg/day of lutein, and are orally administered for a time sufficient for the lutein to be absorbed by the animal.

6. I have reviewed the official action dated April 23, 2002, and the documents: Jyonouchi et al., and Ito et al. For the reasons below I believe the subject matter of the pending claims, that oral administration of lutein and its effect on the immune response, is not suggested to one skilled in the art by the cited documents because, for example:

- a) administration of lutein in Jyonouchi is intraperitoneally and not by feeding or oral administration as in the present invention; and
- b) Jyonouchi teaches local injection near the spleen and thereby creates a highly localized concentration of lutein.

Therefore, it is my opinion that one of ordinary skill in the art could not have reasonably inferred from the Jyonouchi reference that lutein would be absorbed at effective levels following oral administration so as to have the claimed effect on the immune system and immune response in companion animals.

Declaration of Michael Griffin Hayek Under 37 CFR 1.132

Serial No.: 09/291,227

Filed: April 13, 1999

Title: Lutein- Containing Supplement and Process for enhancing Immune Response in Animals

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7. These statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any registration resulting there from.

Signed at Lewisburg, OH, this 16<sup>th</sup> day of July, 2002.

Respectfully submitted,

By: Michael Griffin Hayek

Name: MICHAEL GRIFFIN HAYEK

Title: Director, Strategic Research